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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,852

11/30/2006

Martin M. Lenhardt

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EXAMINER

SMITH, FANGEMONIQUE A

ART UNIT

PAPER NUMBER

3736

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/565,852	<b>Applicant(s)</b> LENHARDT ET AL.	
	<b>Examiner</b> FANGEMONIQUE SMITH	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. This Office Action is responsive to the Request for Continued Examination filed on January 28, 2010. Examiner acknowledges the amendment of claims 1, 2, 8 and 9. Claims 1-14 are pending.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, it is unclear how one will be able to apply intracranial pressure directly to the eyeball of a patient without interference from the skull of the patient, as described by Applicant. The intracranial pressure measures the pressure within the skull. Applicant discloses the pressure applied to the eyeball is able to reach an equilibrium with the pressure within the skull and in turn, provides an intracranial pressure measurement. Upon gaining an equilibrium, the skull, cranial tissue, and cranial fluid together apply an equal and opposite force to the pressure applied to the eyeball. It is unclear how this can be attained without the interference from the skull.

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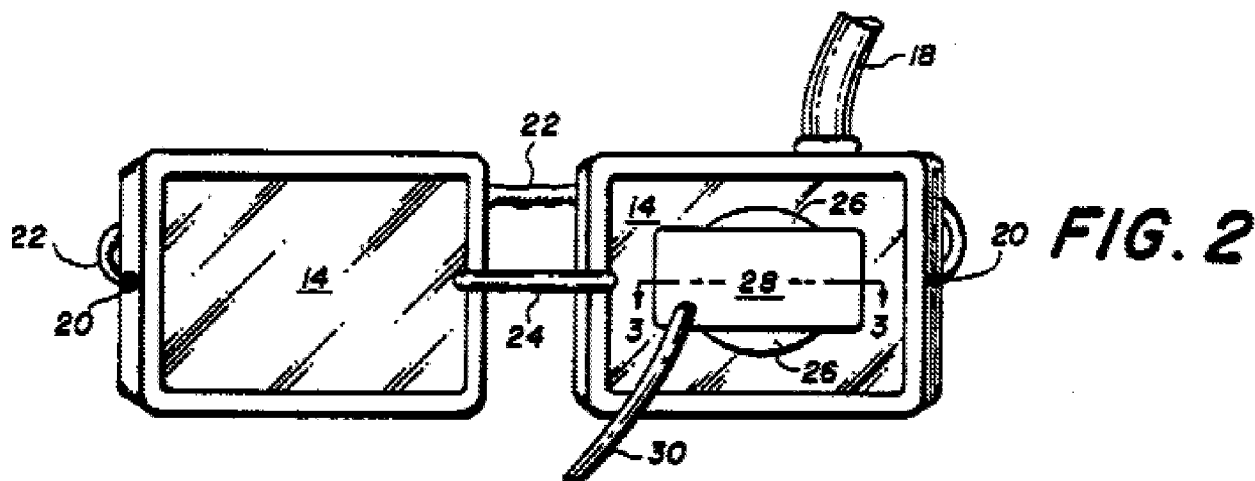
***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-6 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henriquez et al. (U.S. Patent Number 5,129,403) in view of Bridger et al. (U.S. Patent Number 5,919,144).

In regard to claims 1-6 and 8-13, Henriquez et al. disclose a method and apparatus for enabling the detection of acoustic signals that originate in and propagate through the brain. Henriquez et al. disclose disposing a cupping structure with a sensor against the eye socket of a patient for forming an acoustic flow path between the brain and the sensor located on an eyelid of the patient (col. 1, lines 61-68; col. 2, lines 1-29). The Henriquez et al. device is used for detecting and transducing intraocular acoustic signals. The device disclosed by Henriquez et al. includes an analyzer for interpreting the acoustic signals to determine the presence of life threatening diseases in time to safely treat them including (col. 1, lines 54-68; col. 2, lines 1-38). The cupping structure may be adapted to be applied to both eyeballs of the patient having piezoelectric film as part of the sensing mechanism.



The eye garment device is capable of determining the coherency between the two eyes of a patient under testing. In regard to the claims, Henriquez et al. disclose the features of the Applicant's invention as described above. Although Henriquez et al. disclose features of Applicant's invention including gaining acoustic signal information about the brain through contact with the eye of a patient, the Henriquez et al. reference does not specifically disclose gaining intracranial pressure measurements as a result of gaining acoustic signal data from the brain. Also, the Henriquez et al. reference does not specify an ultrasonic range at which the device is to operate. Bridger et al. disclose an apparatus and method for measuring the intracranial pressure of a patient based on acoustic signals received after interaction with the brain. Bridger et al. further disclose the apparatus and method including steps of transmitting an acoustic signal into a cranium at frequencies of less than 100 kHz. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify an apparatus for detecting acoustic signals in a patient, similar to that disclosed by Henriquez et al., to include a method step and corresponding apparatus which allows the acoustic signal range to be set at a lower frequency and the intracranial pressure to be determined, similar to that

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disclosed by Bridger et al., to provide a device and method which can measure intracranial pressure without skull penetration, which poses minimal health risks to a patient during long term monitoring (Bridger et al.- col. 1, lines 48-67; col. 2, lines 1-7).

6. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henriquez et al. (U.S. Patent Number 5,129,403) in view of Bridger et al. (U.S. Patent Number 5,919,144) and in further view of Abreu (U.S. Patent Number 6,423,001).

In regard to claims 7 and 14, the combined references of Henriquez et al. and Bridger et al. disclose the features of the Applicant's invention as described above. The combined references do not specifically disclose the ability to detect retinal artery pulsations as part of the analysis in determining intracranial pressure. Abreu discloses an apparatus and method for detecting physical and chemical parameters of a patient. Abreu further discloses having a mechanism, which is capable of determining retinal artery pulsations of the patient. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify an apparatus for determining absolute intracranial pressure in a patient, similar to that disclosed by the combined Henriquez et al. and Bridger et al. references, to include a mechanism which allows the retinal artery pulsation to be monitored, similar to that disclosed by Abreu, to provide a means to evaluate the amount of intraocular pressure needed for vessels to open (Abreu - col. 79, lines 23-32).

7. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henriquez et al. (U.S. Patent Number 5,129,403) in view of Bridger et al. (U.S. Patent Number 5,919,144) and in further view of Chisum et al. (U.S. Patent Number 3,903,871).

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In regard to claims 7 and 14, the combined references of Henriquez et al. and Bridger et al. disclose the features of the Applicant's invention as described above. The combined references do not specifically disclose the ability to detect retinal artery pulsations as part of the analysis in determining intracranial pressure. Chisum et al. disclose an apparatus for measuring the intracranial pressure in a non-invasive manner. The device detects the blood flow within an optic artery of the patient through the use mechanically applied pressure or suction. The Chisum et al. device is able to determine retinal artery pulsations of the patient to assist with determining the corresponding intracranial pressure. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify an apparatus for determining absolute intracranial pressure in a patient, similar to that disclosed by the combined Henriquez et al. and Bridger et al. references, to include a mechanism which allows the retinal artery pulsation to be detected, similar to that disclosed by Chisum et al., to provide important information regarding body conditions including intracranial pressure information.

### ***Response to Arguments***

8. Applicant argues the prior art references do not disclose operating the device using frequency acoustic signals within an eyeball resonant frequency range of 33-43kHz. Examiner respectfully disagrees. Although the Bridger et al. reference may indicate a range preference, the Bridger et al. reference teaches transmitting acoustic signals into a cranium at frequencies of less than 100 kHz. This disclosure of transmitting acoustic signals at frequencies of less than 100 kHz meets the frequency limitations of Applicant's invention as claimed. Applicant's arguments with respect to the claims have been considered but are not persuasive. The rejection stands.

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9. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is (571)272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736